U.S. Food and Drug Administration
Extra Label Drug Use in Animals

OMB Control No. 0910-0325

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration regulations regarding specific reporting requirements as identified below. The Animal Medicinal Drug Use Clarification Act of 1994 (P.L. 103-396) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to allow veterinarians to prescribe extralabel use of approved new animal drugs. It also permits FDA, if FDA finds that there is a reasonable probability that the extralabel use of an animal drug may present a risk to public health, to establish a safe level for a residue from the extralabel use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level. This requirement is codified at 21 CFR 530.22(b). The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. Accordingly, we request extension of OMB approval of the information collection provisions found in 21 CFR 530.22(b), which requires the development and submission of an analytical methodology for drug residue quantification above any safe level established, as prescribed under the FD&C Act.

2. Purpose and Use of the Information Collection

The analytical method developed would be used by FDA and other State and Federal agencies to assure the safety of the food supply when drugs are used in an extralabel manner. Respondents to the information collection are private sector drug sponsors or veterinary associations, or veterinarians, state, local, and tribal governments, and Federal agencies.

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques. Firms are free to use whatever forms of information technology may best assist them in development and submission of acceptable analytical methodology for drug residue quantification above any safe level established.

4. Efforts to Identify Duplication and Use of Similar Information

   The information collection requires the development and submission of an acceptable analytical methodology for drug residue quantification when such methodology is not available. We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

   We estimate 75% of respondents are small businesses. FDA assists small businesses in complying with its regulatory requirements through Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide guidance on our website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

   Information collection schedule is consistent with statutory requirements under the FD&C Act and applicable agency regulations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the Federal Register of June 26, 2017 (82 FR 28858). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

    Information will be kept confidential in accordance with 18 USC 1905 and 21 USC 331(j), as well as section 301(j) of the FD&C Act.

11. Justification for Sensitive Questions

    This information collection does not contain questions pertaining to sexual behavior, attitude, religious beliefs, or any other matter commonly considered private or of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

This information collection requires reporting of an analytical method for residue detection of an extralabel use in animals of an approved animal or human drug. Although no submissions have been received under the information collection, we believe there will be instances when analytical methodology will be required. Thus, we continue to estimate burden based on the possibility of requiring development and submission of methodology for up to two drugs per year.

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
530.22(b); Submission(s) of analytical method	2	1	2	4,160	8,320

[1] There are no capital r operating and maintenance costs associated with the information collection.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry compliance Officer[1]	8,320	$43.90	$365,248

[1] May 2016 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes131041.htm) $33.77 hourly wage plus 30% adjusted for benefits.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate Federal costs associated with the information collection will be absorbed by existing resource allocations.

15. Explanation for Program Changes or Adjustments

The burden has not changed from the burden shown in the current inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.